K130315

510(K) SUMMARY

JUL 12 2013

Submission Date: July 11th 2013

Submitter Information

Company Name: CyDen, Ltd.
Company Address: Technium 2, Kings Road, Swansea, Wales, UK SA1 8PJ

Contact Person: Dr Mike Kiernan
CyDen
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Device Information

Trade Name: iPulse Hair Removal System

Common Name: Light based over the counter hair removal system

Classification Name: Laser surgical instrument for use in general and plastic surgery and dermatology

Device Class: 21 CFR 878.4810

Predicate Devices:

CyDen iPulse Smoothskin M100 series 2:	K122280
Shaser IPL Hair Removal System Shaser Inc,	K103560
Flash 'N Go Home Skinovations Inc,	K082298

Device Description: The iPulse is an intense pulsed light (IPL) system composed of a base unit housing the electrical and electronic sub-assembly and an umbilical cord which is connected to the applicator, located in which is the source of optical radiation, namely a Xenon flashlamp. The system is powered from AC power via an external power converter.

Intended Use: The iPulse Hair Removal System is an over the counter device intended for the removal of unwanted hair.

Indications for Use: The iPulse Hair Removal System is indicated for the removal of unwanted hair.

Performance Data: Nonclinical, clinical and usability testing has been completed for the iPulse Hair Removal System. Nonclinical testing included biocompatibility, electrical safety and software testing. The iPulse Hair Removal System was tested in a clinical study of 61 subjects. Each subject had 12 weekly treatments under clinical supervision. Gel was used with all treatments. Treatment sites included the leg, arm, bikini and underarm. Hair counts were taken in a fixed area located using a template and skin landmarks. The hair count before and after treatment was recorded from photographs and reviewed by an independent assessor. The reduction in hair density was

calculated. When used as directed, the clinical trial subjects showed on average 31.3% less hair at 6 months.

Comparison to Predicate Device:

The iPulse Hair Removal System has the same intended use, mode of action and similar operational characteristics as the predicate devices. Any minor differences between the iPulse Hair Removal System and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is as safe and as effective as the predicate devices for its intended use. Therefore, the iPulse Hair Removal System may be found substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

Cyden Limited
% Dr. Michael Kiernan
Chief Scientific Officer
Technium 2, Kings Road,
Swansea, Wales, United Kingdom, SA1 8PJ

Re: K130315
Trade/Device Name: iPulse Hair Removal System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: May 30, 2013
Received: June 05, 2013

Dear Dr. Kiernan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130315

Device Name: iPulse Hair Removal System

Indications for Use:

The iPulse Hair Removal System is an over-the-counter device intended for removal of unwanted hair.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.07.12 07:50:29 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number ___K130315____